Place in Site Master File #2

Case report form

Screening form:

NAME	QUESTION	ANSWER	INFO BOX	Note+limit in eCRF
		PATIENT IDENTIFICATION		
S1	National identification number	I__I__I__I__I__I__I__I-I__I__I__I__I	**Denmark:** CPR nummer. If the patient has a fictive CPR number please use the letter D as a prefix, e.g D100255-0jh0 If an unknown patient is identified you have the option to change the fictive CPR number to the correct CPR number. **Switzerland:** The national identification number will consist of 0101 + site id + 01 Site id is system generated **Other countries:** The national identification number will consist of date of birth + site id + 01 Site id is system generated	**Denmark:** RED WARNING A participant with identical CPR number has previously been enrolled in the SUP-ICU trial and cannot be randomised again. If the participant was enrolled at your department, please readmit the patient in the system. If not please contact the coordinating centre for transferal of the patient in the system. contact@sup-icu.com or +45 3545 7450 WARNING if CPR is invalid Format of CPR is not correct. It should be 10 digits long. If a fictive CPR is entered, please use the **prefix 'D'** (capital D) followed by 10 characters. See 'info'. **Other countries:** RED WARNING: (validating on enrolled patients only) The trial participant below with the same national identification number (NIN) has previously been enrolled in the SUP-ICU trial. If the trial participant below is **not** identical to the one you are trying to

				screen, please increase the serial number by 1 (e.g. change 01 to 02). If the trial participant has been enrolled previously, please readmit the patient in the system. For further information please contact contact@sup-icu.com or +45 3545 7450 YELLOW WARNING: (Validating on enrolled patients in the **same country** with the **same birthday**) The trial participants listed below are potentially identical with the one you are trying to screen. Please check the list below. If the trial participant you are trying to screen is NOT identical to any of the participants below, please **press accept** to continue. If the patient has been enrolled previously, please readmit the patient in the system. For further information please contact contact@sup-icu.com or +45 3545 7450 Warning if NIN of an excluded patient is entered again: A patient with the same NIN has previously been excluded. If you want to screen the patient again, please press accept. For further information please contact contact@sup-icu.com or +45 3545 7450

INCLUSION CRITERIA				
S2	Was the patient acutely admitted to the ICU?	Yes No	Acute admission: a non-planned ICU admission. It does NOT include: 1) planned recovery after surgery or similar planned admission 2) admission to semi intensive care, intermediate intensive care or similar bed.	
S3	Age ≥ 18 years?	Yes No		
S4	Systolic blood pressure < 90 mmHg or mean arterial pressure < 70 mmHg?	Yes No		
S5	Ongoing continuous treatment with vasopressors or inotropes (any of the following: noradrenaline, phenylephrine, vasopressin, terlipressin, dopamine dobutamine, adrenaline, milrinone or levosimendan)	Yes No		
S6	Lactate > 4 mmol/l	Yes No		
S7	Renal replacement therapy (acute or chronic intermittent or continuous renal replacement therapy)	Yes No		
S8	Invasive mechanical ventilation which is expected to last > 24 hours. If in doubt of the forecast answer 'YES'.	Yes No		
S9	Acute coagulopathy documented within the last 24 hours (definition in INFO)	Yes No	Platelets < 50 x 10^9/l or INR > 1.5 or PT > 20 seconds	
S10	History of coagulopathy within 6 months prior to hospital admission. (definition in INFO)	Yes No	Platelets < 50 x 10^9/l or INR > 1.5 or PT > 20 seconds	

S11	History of chronic liver disease?	Yes No	Portal hypertension, cirrhosis proven by biopsy, computed tomography (CT) scan or ultrasound, history of variceal bleeding or hepatic encephalopathy in the past medical history	
S12	Ongoing treatment with anti-coagulants (definition in INFO) Prophylactic doses of low molecular weight heparin/heparin and acetylsalicylic acid are NOT included	Yes No	Anticoagulant drugs includes: • Dipyridamole • Vitamin K antagonists • ADP-receptor inhibitors • Therapeutic doses of low molecular weight heparin • New oral anticoagulant drugs • Intravenous direct thrombin (II) inhibitors • Similar drugs	
EXCLUSION CRITERIA				
S13	Contraindications to proton pump inhibitor?	Yes No	Including intolerance of PPI and treatment with atazanavir (HIV medication)	
S14	Ongoing treatment with proton pump inhibitor or histamine-2-receptor antagonist on a daily basis?	Yes No	If PPI/H2RA is discontinued in ICU answer NO. If PPI/H2RA is continued in ICU answer YES.	
S15	GI bleeding of any origin during current hospital admission?	Yes No		
S16	Peptic ulcer confirmed by endoscopy or other method during current hospital admission?	Yes No		
S17	Withdrawal from active therapy or brain death?	Yes No		
S18	Organ transplant during current hospital admission?	Yes No		
S19	Known pregnancy?	Yes No	In fertile women a negative urine-hCG or plasma-hCG is needed	
S20	Consent according to national regulations not obtainable?	Yes No		
STRATIFICATION VARIABLES				
S21	Name of the patient **Switzerland**	_____	Will be shown in the medication dispensing system. If the trial participant is unknown,	

	Patient initials		please click the 'unknown at admission' check box.	
S22	Haematological malignancy?	Yes No	Includes any of the following: • leukemia: Acute lymphoblastic leukemia (ALL), acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), chronic lymphocytic leukemia (CLL) • lymphoma: Hodgkin's disease, Non-Hodgkin lymphoma (e.g. small lymphocytic lymphoma (SLL), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), mantle cell lymphoma (MCL), hairy cell leukemia (HCL), marginal zone lymphoma (MZL), Burkitt's lymphoma (BL), post-transplant lymphoproliferative disorder (PTLD), T-cell prolymphocytic leukemia (T-PLL), B-cell prolymphocytic leukemia (B-PLL), Waldenström's macroglobulinemia, other NK- or T-cell lymphomas • Multiple myeloma/plasma cell myeloma	
s23	Site		Automatically generated in the eCRF	
s24	Vial identifier number		Automatically generated in the eCRF	
s25	Randomisation time stamp		Automatically generated in the eCRF	

Date:

Name of person completing the form:

Signature:

Baseline form

NAME	QUESTION	ANSWER	INFO	Note+limit in eCRF
GENERAL INFORMATION				
BL1	Male sex	Yes No		
BL2	ICU admission date	I__I__I-I__I__I-I__I__I__I__I Format: dd-mm-yyyy	If the patient was transferred directly from another ICU, please write the date of admission to the first ICU	Date and time before randomisation
BL3	ICU admission time	I__I__I:I__I__I Format: hh:mm (24 hours format)	If the patient was transferred directly from another ICU, please write the time of admission to the first ICU	Date and time before randomisation
BL4	Hospital admission date	I__I__I-I__I__I-I__I__I__I__I Format: dd-mm-yyyy	If the patient was transferred from another hospital, report the date of admission to the first hospital.	Date more than 30 days prior to ICU admission has to be accepted
BL5	Elective surgery within 7 days prior to ICU admission during current hospital admission?	Yes No	Surgery scheduled 24 hours or more in advance. Includes surgery at another hospital.	
BL6	Emergency surgery within the last 24 hours?	Yes No	Surgery added to the operating room plan 24 hours or less prior to surgery. Includes surgery at another hospital.	
BL7	Treatment of *clostridium difficile* during current hospital admission?	Yes No	Treatment includes: Vancomycin (enteral), Metronidazole (enteral or intravenous) or Fidaxomicin (enteral)	
BL8	Treatment with NSAIDs or acetylsalicylic acid in any dose at hospital admission?	Yes No		
BL9	Treatment with anti-coagulants at hospital admission? (definition in INFO) Prophylactic doses of low molecular	Yes No	**Includes** • Vitamin K antagonists (e.g. Warfarin) • Dipyridamole (e.g. Persantine) • ADP-receptor inhibitors (e.g. Clopidogrel, Prasugrel, Ticagrelor) • Therapeutic doses of low	

	weight heparin/heparin and acetylsalicylic acid are NOT included		molecular weight heparin • New oral anticoagulant (factor IIa and Xa inhibitors, e.g Dabigatran, Apixaban, Xarelto) • Intravenous direct thrombin (II) inhibitors (e.g. Bivalirudin) • Similar drugs	
BL10	Intravenous thrombolysis within the previous 3 days?	Yes No		
CO-MORBIDITIES **The registration below is based on information from the patient's files** **PLEASE READ THE INFO BOXES!**				
BL11	Chronic lung disease?	Yes No	Chronic obstructive pulmonary disease (COPD), asthma or other chronic lung disease or treatment with any relevant drug indicating this at admission to hospital	
BL12	Previous myocardial infarction?	Yes No		
BL13	Chronic heart failure (NYHA III-IV)?	Yes No	New York Heart Association Functional Class (NYHA) III-IV. NYHA III: The patient has marked limitations in physical activity due to symptoms (fatigue, palpitation or dyspnoea) even during less than ordinary activity (walking short distances 20-100 m. or walking up stairs to 1st floor). The patient is only comfortable at rest. NYHA class IV: The patient is not able to carry out any physical activity (without discomfort (fatigue, palpitation or dyspnoea)). Symptoms are present even at rest and the patient is mostly bedbound	
BL14	Chronic renal replacement therapy within the last year prior to hospital admission?	Yes No		
BL15	Treatment with at least 0.3 mg/kg/dayof prednisolone equivalent for at least 1 month in the 6 months prior	Yes No	For a 70 kg person this equals 21 mg per day for at least one month in the 6 months prior to ICU admission	

	to ICU admission?			
BL16	Metastatic cancer?	Yes No	Proven metastasis by surgery, CT scan or any other method	
BL17	AIDS?	Yes No	HIV positive patients with one or more HIV defining diseases such as pneumocystis jerovechii pneumonia, Kaposi's sarcoma, Lymphoma, tuberculosis or toxoplasma infection	
SAPS 2 (Simplified Acute Physiology 2) Score and SOFA (Sequential Organ Failure Assessment) Score The registration below is based on values obtained in the 24 hours prior to randomisation. Please select the most deranged values (from general ward, ICU or other)				
BL18	Lowest Glasgow coma score in the 24 hours prior to randomisation. (If sedated, use last score before sedation? If unknown write 15) (Info for instruction)	I__I__I	If not scored in the last 24 hours, use the last available GCS-score. Glasgow Coma Score is the sum of points (range 3-15) given for the following categories: eyes, verbal response, and motor response. **EYES**: 1 point: Does not open eyes. 2 points: Opens eyes in response to painful stimuli. 3 points: Opens eyes in response to voice. 4 points: Opens eyes spontaneously **VERBAL:** 1 point: Makes no sounds. 2 points: Incomprehensible sounds. 3 points: Utters inappropriate words. 4 points: Confused, disorientated. 5 points: Oriented, converses normally. **MOTOR:** 1 point: Makes no movements. 2 points: Extension to painful stimuli. 3 points: Abnormal flexion to painful stimuli 4 points: Flexion / withdrawal to painful stimuli. 5 points: Localizes painful stimuli. 6 points: Obeys commands.	Limit: 3-15 Values outside range cannot be accepted
BL19	Was the core temperature ≥ 39°C (102.2 Fahrenheit) in the 24 hours prior to randomisation?	Yes No	Core temperature: rectal, urinary bladder, central line, or tympanic. If oral, inguinal or axillary temperatures are used, add 0.5°C to measured value	
BL20	Urinary output in the 24 hours prior to randomisation? If urine volume is measured for a short period MULTIPLY TO GET TOTAL OUTPUT IN 24 HOURS! (ml)	I__I__I__I__I		Limit: 0-8000 No decimals
BL21	Lowest systolic arterial pressure in the 24 hours prior to randomisation? (mmHg)	I__I__I__I		Limit: 70-150 No decimals
BL22	Highest systolic arterial pressure	I__I__I__I		Limit: 70-150 No decimals

	in the 24 hours prior to randomisation? (mmHg)			
BL23	Lowest mean arterial pressure (MAP) in the 24 hours prior to randomisation? (mmHg)	I__I__I__I	If mean arterial pressure (MAP) is not calculated by monitoring equipment, use the manual sphygmomanometer recording of systolic (SBP) and diastolic blood pressure (DBP) to obtain MAP using this equation MAP = (DBP x 2 + SBP) /3	Limit 45-150 No decimals
BL24	Lowest heart rate in the 24 hours prior to randomisation?	I__I__I__I	If the patient has an atrial arrhythmia, measure the ventricular response rate (R waves) only to record the heart rate.	Limit 40-200 No decimals
BL25	Highest heart rate in the 24 hours prior to randomisation? (beats/min)	I__I__I__I	If the patient has an atrial arrhythmia, measure the ventricular response rate (R waves) only to record the heart rate.	Limit 40-200 No decimals
BL26	Highest dose of noradrenaline (norepinephrine) in the 24 hours prior to randomisation? (µg/kg/min)	I__I__I__I__I	Administration of the drug for at least 1 hour. Otherwise write 0. Does not include boli.	Limit: 0-2.00 0,1 or 2 decimals
BL27	Highest dose of adrenaline in the 24 hours prior to randomisation? (µg/kg/min)	I__I__I__I	Administration of the drug for at least 1 hour. Otherwise write 0. Does not include boli.	Limit: 0-0.50 0,1 or 2 decimals.
BL28	Highest dose of dopamine in the 24 hours prior to randomisation? (µg/kg/min)	I__I__I__I	Administration of the drug for at least 1 hour. Otherwise write 0. Does not include boli.	Limit: 0-10.0 0,1 or 2 decimals
BL29	Did the patient receive dobutamine, vasopressin, phenylephrine, milrinone or levosimendan in the 24 hours prior to randomisation?	Yes No		
BL30	Lowest p-sodium (p-natrium) in the 24 hours prior to randomisation? (mmol/l)	I__I__I__I		Limit: 100-160 No decimals cannot be higher than B31
BL31	Highest p-sodium			Limit: 100-

	(p-natrium) in the 24 hours prior to randomisation? (mmol/l)	I__I__I__I		160 No decimals cannot be lower than B30
BL32	Lowest p-potassium (p-kalium) in the 24 hours prior to randomisation? (mmol/l)	I__I__I		Limit: 2.0-6.0 0 or 1 decimal. Cannot be higher than B33
BL33	Highest p-potassium (p-kalium) in the 24 hours prior to randomisation? (mmol/l)	I__I__I		Limit: 2.0-6.0 0 or 1 decimal. Cannot be lower than B32
BL34	Lowest white blood cell count in the 24 hours prior to randomisation? (10^9 /l)	I__I__I__I	To convert from mm^3 divide with 1000 If the lab returns a value of e.g. "<0.1", please report "0.1".	Limit: 0.1-400 0 or 1 decimal. Cannot be higher than B35
BL35	Highest white blood cell count in the 24 hours prior to randomisation? (10^9 /l)	I__I__I__I	To convert from mm^3 divide with 1000 If the lab returns a value of e.g. "<0.1", please report "0.1".	Limit: 0.1-400 0 or 1 decimal. Cannot be higher than B34
BL36	Lowest platelet count? (10^9/l)	I__I__I__I	To convert from mm^3 divide with 1000 If the lab returns a value of e.g. < 3, please report 3	Limit: 3-800 No decimals
BL37	Highest bilirubin in the 24 hours prior to randomisation? (µmol/l) If no value is obtained, write the first value from the 24-hour period after randomisation.	I__I__I__I	To convert from mg/dl multiply with 17.1	Limit: 5-300 No decimals
BL38	Highest creatinine in the 24 hours prior to randomisation ? (µmol/l) If no value is obtained, write the first value from the 24-hour period after	I__I__I__I__I	To convert from mg/dl multiply with 88.4	Limit: 40-1000 No decimals

	randomisation.			
BL39	Highest carbamid (urea) in the 24 hours prior to randomisation? (mmol/l). If no value is obtained, write the first value from the 24-hour period after randomisation.	I__I__I__I	To convert from mg/dl multiply with 0.05	Limit: 2-40 0 or 1 decimal
BL40	Lowest s-bicarbonate ($HCO3^-$) in the 24 hours prior to randomisation? (mmol/l)	I__I__I__I	mmol/l = mEq/l	Limit: 5-40 0 or 1 decimal
Enter values for **the lowest PaO2/FiO2-ratio** in the 24 hours prior to randomisation. **Do not enter the ratio itself!** **Please report the corresponding PaO2 and FiO2**				
BL41	PaO2 (kPa)	I__I__I__I	To convert from mmHg: multiply by 0.133	Limit: 5-40 0 or 1 decimal
BL42	FiO2 (%)	I__I__I__I	For calculation of FiO2 use the list below: Nasal catheter: flow of oxygen and corresponding FiO2 0 L: 21 % 1 L: 27 % 2 L: 33 % 3 L: 37 % 4 L: 40 % 5 L: 44 % 6 L: 48 % Hudson mask: flow of oxygen / air flow and corresponding FiO2 0 L: 21 % 3 / 12 L: 29 % 7,5 / 7,5 L: 41 % 10 / 5 L: 48 % 15 / 0 L: 59 % High flow oxygen via nasal cannula: flow of oxygen and corresponding FiO2 10 L: 62 % 15 L: 82 % 20 L: 90 % 30 L: 95 % Please report the corresponding PaO2 and FiO2 that give the lowest ratio. Hudson mask: flow of oxygen / air flow and corresponding FiO2 0 / 15 L: 21 % 3 / 12 L: 29 % 7,5 / 7,5 L: 41 %	Limit 21-100 Values outside range cannot be accepted. 0 or 1 decimal

			10 / 5 L: 48 % 15 / 0 L: 59 % Example 1: 1 patient has 2 corresponding measurements of FiO2 and PaO2. #1: PaO2 in the arterial blood gas was 8 kPa. The patient had a Hudson mask with 15 L oxygen flow. The corresponding FiO2 was 59% (see above). Thus, the PaO2/FiO2 was 8/0,59 = 13,6 kPa. #2: PaO2 in the arterial blood gas was 9 kPa. The patient had a nasal catheter with 6 l oxygen flow. The corresponding FiO2 was 48% (see above). Thus, the PaO2/FiO2 was 9/0,36 = 18,8 kPa. Measurement number 1 gives the lowest ratio and must be reported.	
BL43	Respiratory support (invasive or non-invasive ventilation including continuous mask CPAP or CPAP via a tracheotomy) in the 24 hours prior to randomisation?	Yes No	Intermittent CPAP is NOT considered mechanical ventilation	

Date:

Name of person completing the form:

Signature:

Day form

NAME	QUESTION	ANSWER	INFO	NOTE+LIMIT
	GENERAL INFORMATION			
D1	Was the trial medication delivered to the patient on this day?	Yes No		
D2	Treatment with open-label proton pump inhibitor or histamine-2-receptor antagonist on this day? **IF YES:** Reason for treatment with PPI/H2RA (choose one only): a) Clinical indication for treatment with PPI/H2RA because of GI bleeding, verified ulcer/varices/gastritis or as part of a bowel rest regimen? b) Prophylaxis/treatment for other reasons than described above? (is considered a protocol violation)	Yes No Yes No Yes No	Use of PPI/H2RA as stress ulcer prophylaxis and treatment without an obvious indication is considered a protocol violation	If 'YES' answer a and b Either a OR b has to be answered 'YES'. Only 'YES' in either a or b. If 'YES' in a: Warning! PLEASE **DISCONTINUE** TRIAL INTERVENTION AND COMPLETE WITHDRAWAL FORM If 'YES' in b: Warning! PLEASE **CONTINUE** TRIAL INTERVENTION AND DISCONTINUE OPEN-LABEL THERAPY
D3	Respiratory support (invasive or non-invasive ventilation including continuous mask CPAP or CPAP via a tracheotomy) on this day?	Yes No	Intermittent CPAP is NOT considered mechanical ventilation	
D4	Continuous treatment with vasopressor and/or inotrope	Yes No	Continuous treatment with norepinephrine, epinephrine, dobutamine, dopamine, vasopressin, levosimendan, phenylephrine or milrinone at any time during the day	
D5	Renal replacement therapy on this day? (including days between intermittent renal replacement therapy)	Yes No	Any type of acute and chronic renal replacement therapy is included (e.g. dialysis)	
D6	Onset of pneumonia on this day? PLEASE READ criteria for pneumonia in INFO!	Yes No	Two or more serial chest radiographs with at least one of the following (one radiograph is sufficient for patients with no underlying pulmonary or cardiac disease):	

			1. new or progressive *and* persistent infiltrate 2. consolidation 3. cavitation AND at least one of the following: 1. fever (>38°C) with no other recognised cause 2. leucopaenia (white cell count < 4 x 109/l) or leucocytosis (white cell count >12 x 109/l) AND at least two of the following 1. new onset of purulent sputum or change in character of sputum, or increased respiratory secretions or increased suctioning requirements 2. new onset or worsening cough, or dyspnoea, or tachypnoea 3. rales or bronchial breath sounds 4. worsening gas exchange (hypoxaemia, increased oxygen requirement, increased ventilator demand)	
D7	Treatment for suspected or documented clostridium difficile enteritis on this day? Definition of treatment in info.	Yes No	Treatment includes Vancomycin (enteral), Metronidazole (enteral or intravenous) and Fidaxomicin (enteral)	
D8	Acute myocardial ischemia on this day? PLEASE READ criteria for acute myocardial ischemia in INFO!	Yes No	**- ST-elevation myocardial infarction** **OR** **- Non-ST elevation myocardial infarction** **OR** **- Unstable angina pectoris** according to the criteria in the clinical setting in question (e.g. elevated biomarkers, ischemic signs on ECG and clinical presentation) **AND**	

			the patient receiving treatment as a consequence of this (reperfusion strategies (PCI/thrombolysis) or initiation/increased antithrombotic treatment)	
D9	Enteral feeding and/or oral nutritional intake on this day?	Yes No		
D10	Number of units of red blood cells transfused during this day?	I__I__I		Limit: 0-15 No decimals
BLEEDING FORM				
B1	Did the patient have hematemesis, coffee ground emesis, melena, haematochezia or bloody nasogastric aspirate on this day?	Yes No		If 'YES' in B1 B2-B7 have to be answered. Otherwise proceed to SAR1-SAR7
B2	Did the patient have spontaneous drop of systolic, diastolic or, mean arterial pressure of **20 mmHg** or more within 24 hours after the bleeding episode and in absence of other causes?	Yes No		
B3	Was vasopressor initiated or increased by 20% or more within 24 hours after the bleeding episode and in absence of other causes?	Yes No	Vasopressors include: noradrenaline, adrenaline, dopamine, vasopressin or terlipressin	
B4	Did the haemoglobin decrease by at least 2 g/dl (1.24 mmol/l) within 24 hours after the bleeding episode and in absence of other causes?	Yes No		
B5	Did the patient receive 2 units of packed red blood cells or more within 24 hours after the bleeding episode and in absence of other causes?	Yes No		
B6	Was the origin of the bleeding confirmed? IF YES:	Yes No		If 'YES' mark <u>at least one</u> option below
	Gastric or duodenal ulcer?	Yes No		
	Gastritis?	Yes No		
	Bleeding oesophageal Varices?	Yes No		
	Other?	Yes No		

B7	Was endoscopy, open/laparoscopic surgery or coiling performed? **IF YES:**	Yes No		If 'YES' mark <u>at least one</u> option below
	Endoscopy? Open/laparoscopic surgery? Coiling?	Yes No Yes No Yes No		
SERIOUS ADVERSE REACTIONS PLEASE READ THE INFO. If the patient experiences a SAR the trial intervention has to be stopped and the coordinating centre has to be contacted at contact@sup-icu.com or +45 3545 7450 within 24 hours. . Please complete withdrawal form, continue daily registration and complete follow-up.				
SAR1	Anaphylactic reaction related to the intervention on this day?	Yes No	Urticaria **<u>and</u>** at least one of the following • Worsened circulation (>20% decrease in blood pressure or >20% increase in vasopressor dose) • Increased airway resistance (>20% increase in the peak pressure on the ventilation) • Clinical stridor or bronchospasm • Subsequent treatment with bronchodilators	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450
SAR2	Agranulocytosis related to the intervention on this day?	Yes No	Any new, acute and severe drop in granulocytes to < 0.5 x 10^9/l requiring active monitoring or treatment	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450
SAR3	Pancytopenia related to the intervention on this day?	Yes No	Any new, severe drop in red blood cells, white blood cells <u>and</u> platelets requiring active monitoring or treatment	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450

SAR4	Acute hepatic failure related to the intervention on this day?	Yes No	Severe and progressing hepatic failure as judged by the treating doctor or the investigator	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450
SAR5	Steven-Johnson syndrome or toxic epidermal necrolysis related to the intervention on this day?	Yes No	Severe dermatological reactions with a skin biopsy confirming the diagnosis	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450
SAR6	Interstitial nephritis related to the intervention on this day?	Yes No	Nephritis affecting the interstitium of the kidneys surrounding the tubules with a kidney biopsy confirming the diagnosis	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450
SAR7	Angioedema (Quincke's oedema) related to the intervention on this day?	Yes No	A vascular reaction involving the deep dermis, subcutaneous or submucosal tissues, resulting in a characteristic localized oedema.	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form contact the coordinating centre within 24 hours at contact@sup-icu.com or +45 3545 7450

Date:
Name of person completing the form:
Signature:

Discharge and readmission form

NAME	QUESTION	ANSWER
	DISCHARGE	
DI1	Date of ICU discharge (dd-mm-yyyy)	I__I__I-I__I__I- I__I__I__I__I
DI2	Time of ICU discharge (24 hours (hh:mm))	I__I__I:I__I__I
DI3	Patient discharge to (**choose one only)** General ward ICU participating in the SUP-ICU trial ICU not participating in the SUP-ICU trial Dead	 Yes No Yes No Yes No Yes No
DI4	Has the patient been enrolled in other interventional trials during this ICU admission?	Yes No
	READMISSION	
DI5	Date of ICU readmission (dd-mm-yyyy)	I__I__I-I__I__I- I__I__I__I__I
DI6	Time of ICU readmission (24 hours (hh:mm))	I__I__I:I__I__I

Date:

Name of person completing the form:

Signature:

Withdrawal form

PLEASE ANSWER ALL QUESTIONS AND CONTINUE DAILY REGISTRATION IF CONSENT HAS NOT BEEN WITHDRAWN

NAME	QUESTION	ANSWER	INFO	NOTE+LIMIT
	WITHDRAWAL FROM INTERVENTION AND/OR DATA REGISTRATION			
W1	Date of withdrawal (dd-mm-yyyy)	I__I__I-I__I__I-I__I__I__I__I		
W2	Time of withdrawal (24 hours (hh:mm))	I__I__I:I__I__I		
W3	Reason for withdrawal (mark <u>one</u> answer): a) Indication for treatment with open label PPI/H2RA b) Clinical decision other than the above c) SAR/SUSAR d)Consent not given or withdrawn	 Yes No Yes No Yes No Yes No Yes No		
W4a	Who is not giving or withdrawing consent? Relative/next of kin/guardian not giving or withdrawing consent Patient not giving or withdrawing consent	 Yes No Yes No		Only to be answered if YES in W3
W4b	Will further daily data be registered?	Yes No	'NO' is only an option if consent has been withdrawn	Only to be answered if YES in W3

Date:

Name of person completing the form:

Signature:

Follow-up form

NAME	QUESTION	ANSWER
F1	Was the patient dead at date for follow-up?	Yes No
F2	If 'YES': Date of death (dd-mm-yyyy)	I__I__I-I__I__I-I__I__I__I__I

Date:

Name of person completing the form:

Signature: